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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,828

06/26/2006

Tsutomu Ishihara

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08/03/2009

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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,828	Applicant(s) ISHIHARA ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 20-22 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-3, 5-19 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/22/2009 and 7/15/2009 has been entered.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 102 and 103

The rejection of claims 2-3, 6, 8-12, 15 and 19 under 35 U.S.C. 102(b) as being anticipated by WO 9941298 (WO '298) is maintained. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over WO 9941298 (WO '298) in view of US 6159381 ('381) is maintained. The rejection of claim 27 under 35 U.S.C. 103(a) as being unpatentable over WO 9941298 (WO '298) is maintained.

Applicant argues that the amended claims are closed and organic polymers of WO '298 have been excluded.

Applicant's arguments have been fully considered but are not found persuasive. Although the term "consists of" in claim 2 and "in the absence of other ingredients" in claim 3 is recited, the Examiner does not interpret the contents of the nanoparticle in either claim 2 or 3 to be closed. There are multiple interpretations of the claim language (see ***Claim Rejections - 35 USC § 112*** below), and for the purposes of comparing the claims to the prior art, the Examiner adopts the interpretation that the contents may be open to lipophilic components (i.e. organic polymers) as implied by the recitation of "fat-solubilized". In this interpretation, the above grounds of rejection still hold against the amended claims for the reasons of record.

The rejection of claims 3 and 11-18 under 35 U.S.C. 102(b) as being anticipated by WO 03033592 (WO '592) is maintained. The rejection of claim 5 under 35 U.S.C. 103(a) as being unpatentable over WO 03033592 (WO '592) in view of US 37017435 ('745) is maintained.

Applicant argues that the structure and function of oleic acid negative ion as instantly claimed is patentably distinguishable from the non-ionic sorbitan ester of oleic acid of '745.

Applicant's arguments have been fully considered but are not found persuasive. Claim 3 is a product-by-process claim. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious

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from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113. It is unclear if the surfactant of claim 3 is a component in the final nanoparticle. It's reasonable that the surfactant may serve only as a solubilizing agent, and not be present in the product nanoparticle (see ***Claim Rejections - 35 USC § 112*** below). In this interpretation, the nanoparticle rendered obvious by WO '592 in view of '745 would be structurally identical to the presently claimed nanoparticle. The presently claimed nanoparticle does not require the presence of a surfactant in the nanoparticle.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-3 and 5-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recites “to act with each other”. It is unclear in what way the primary nanoparticles and salts “act”. Does this mean to react with each other? Does this mean to be combined together? Does this mean to be mixed together?

Claims 2 and 3 recite "fat-solubilized water-soluble drug". It is unclear what constitutes a "fat-solubilized drug". Does this mean a drug that has been chemically

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altered to be fat-soluble? Does this mean a drug that is dissolved in fat? If the drug is dissolved in fat, does "fat" here mean animal lipids (the strict definition of "fat"), or can this be any lipophilic medium? Claim 2 uses closed language to describe the contents of the primary nanoparticle (i.e. "consists of"), but it is unclear if fat is a required additional and unrecited component to make the drug "fat-solubilized". Therefore, it is unclear if the contents of the nanoparticle are truly limited to the recited components. It is similarly unclear if the contents of the nanoparticle of claim 3 are truly limited to the recited components. Claim 3 states that the primary nanoparticle are produced by causing the recited ingredients to act with each other, in the absence of any other ingredients. But as "fat-solubilized" implies the presence of additional ingredients, it is unclear if the contents of the nanoparticle are truly limited to the recited components. Furthermore, there is no positive limitation that even the recited components must be part of the nanoparticle. "To act with each other" is unclear for the reasons above. Does the action result in all components being incorporated in the nanoparticle? For example, it's reasonable that the surfactant may serve only as a solubilizing agent, and not be present in the product nanoparticle. The recited fatty acids are also known solubilizing agents, and may not necessarily be present in the product nanoparticle. For the reasons given above, it is unclear what components are and are not present in the nanoparticle of claims 2 and 3.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

July 31, 2009